

REMARKS

Applicant has preliminarily amended the claims of the present application to bring the application into conformance with the U.S. form for a patent application by removing multiple dependency from certain claims.

Applicant respectfully submits that care has been taken in amending the application and that no new subject matter has been introduced into the application as a result of the foregoing amendments.

Applicant further respectfully submits that claims 1-20, as currently amended, are patentably distinguishable over the references cited by the Examiner in the parent application, namely, JP 09121781; Barker, U.S. Pat. No. 3,920,857; and Rothfuss, U.S. Pat. No. 4,762,658, taken either alone or in combination. Specifically, Applicant respectfully submits that there is a difference between pure lecithin, containing mainly phosphatidylcholine, and glycerophosphatidylcholine, whereby said glycerophosphatidylcholine is not contained in lecithin. The crude lecithin and de-oiled lecithin mentioned in the cited references do not contain glycerophosphatidylcholine. Moreover, the physical properties of pure lecithin, namely phosphatidylcholine, strongly differs from those of glycerophosphatidylcholine, as is well known to one of skill in the relevant art.

With regard to the JP 09121781 reference, Applicant has enclosed herewith an English-language abstract of said reference obtained from Chemical Abstracts (Ex. A), which Applicant respectfully submits provides a better description of the disclosure of said reference. As demonstrated by the enclosed abstract, the known composition contains "crude lecithin", which comprises an oil-like liquid substance, resulting from the

high content of approximately 40% soybean oil (as shown in Table 6, p. 203 from *Kirk-Othmer Encyclopedia of Chemical Technology, Fourth Edition, Vol. 15* (Ex. B)).

Furthermore, the general idea of the JP 09121781 reference is to use a porous mineral material having a large adsorption surface area for the purpose of adsorbing a liquid and oil-containing crude lecithin, where by this adsorption a powder is generated. In other words, the known product is crude lecithin, and the soybean oil contained in that crude lecithin is adsorbed on the surface of the mineral material (i.e., tricalcium phosphate, bone power, or whey calcium) to prevent the “bleeding”, as described in the abstract previously provided by the Examiner in the parent case (in the section entitled “Solution”).

In contrast, the glycerophosphatidylcholine of Applicant’s invention is itself a powder, and does not contain any soybean oil. Moreover, claim 1 of the present application is not directed to a powder, but to a composition which is a granulate—i.e., powder particles which are aggregated to form granules having the advantages described in the present application at page 4, line 20 – page 7, line 6.

Applicant respectfully points out that the present invention is neither directed to a mixture of a powder with an oil-containing liquid (namely, crude lecithin), as described in the JP 09121781 reference, nor to a mixture of two powders (namely, pure lecithin with a small amount of tricalcium phosphate added as a flowing aid), as described in the Barker reference. To the contrary, the present claim 1 is directed to a granulate, being a close-packed arrangement of many particles of glycerophosphatidylcholine together with many particles of the granulation aid, whereby these agglomerations (granulates) surprisingly display the advantage of having permanently suppressed hygroscopic

properties. Moreover, the Barker reference is not relevant due to the fact that a flowing aid is described, consisting of agglomerated non-fat dry milk and agglomerated whey, and that the lecithin described by that reference comprises a crude lecithin consisting of “approximately two-thirds lecithin and one-third oil” (Col. 1, lines 38-39).

Furthermore, with regard to the Rothfuss reference, this reference is also not relevant to the present invention, inasmuch as it describes a method of tableting granular lecithin, using a de-oiled soybean lecithin (sold under the commercial name CENTROLEX) as a starting material. As the attached Ex. B demonstrates, this lecithin does not contain any glycerophosphatidylcholine. Even more importantly, a tablet is not a granulate. Also, while Rothfuss does discuss the problem of reducing hygroscopicity, it teaches that this problem can be addressed by either reducing the relative humidity of the starting material (Col. 2, lines 57-65) or by coating tablets produced by the disclosed method with shellac (Col. 4, line 9).

In summary, Applicant respectfully submits the following:

- that none of the references cited in the parent case describe a granulate containing glycerophosphatidylcholine and the granulation aid mentioned in Applicant's claim 1;
- that all of the cited prior art references use either crude lecithin (an oil-containing lecithin) or de-oiled lecithin as a starting material;
- that only one of the cited references, namely Rothfuss, discusses the problem of hygroscopicity of phospholipidic compositions, which it solves by teaching reduction of the relative humidity and/or coating of the tablet;
- that glycerophosphatidylcholine is not contained in lecithin; and

• that the flowing aid mentioned in Barker is not a granulation aid according to the present invention, due to the fact that a flowing aid acts differently than a granulation aid. The main effect of a flowing aid is to avoid the agglomeration of powder particles, while a granulation aid causes such agglomeration and the generating of granulates.

In view of the foregoing, Applicant respectfully submits that the application is now in condition for substantive examination, and the same is respectfully solicited.

Should anything further be required, a telephone call to the undersigned at (312) 456-8400 is respectfully solicited.

Respectfully submitted,

GREENBERG TRAURIG, P.C.

A handwritten signature in cursive script, appearing to read "Herbert H. Finn", written over a horizontal line.

Herbert H. Finn

One of Attorneys for Applicant

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